510(k) Summary
for the Daytona Anterior Cervical Cage

AUG 2 9 2011

In accordance with 21 CFR 807.92 of the Federal Code of Regulations
the following 510(k) summary is submitted for the Daytona Anterior Cervical Cage.

Date Prepared: March 11, 2011

1. **Submitter:**
King Floyd
SpineNet, LLC
1300 Minnesota Ave
Winter Park, FL 32789
Telephone: 407-539-2483

Contact Person:
J.D. Webb
The OrthoMedix Group, Inc.
1001 Oakwood Blvd
Round Rock, TX 78681
Telephone: 512-388-0199

2. **Trade name:** Daytona Anterior Cervical Cage
Common Name: intervertebral body fusion device
Classification Name: intervertebral body fusion device - cervical
21 CFR section 888.3080
ODP
Class II

3. **Predicate or legally marketed devices which are substantially equivalent:**
Spinal Elements Crystal Cervical Cage (K073351)
Zimmer BAK/C Vista Interbody Fusion (P980048 S3)
Integra Cervical Cage - Calvary Spine LLC (K082260)

4. **Description of the device:**
The Daytona Anterior Cervical Cage system was developed as an intracorporeal implant for anterior cervical spondylodesis. The Daytona Anterior Cervical Cage is a system of wedge shaped implants and instruments designed for anterior cervical interbody fusion (ACIF). To prevent migration, the Daytona Anterior Cervical Cage has teeth on its superior and inferior surfaces.

Materials:
PEEK conforming to ASTM F2026
Tantalum according to ASTM F560

Function:
Maintain adequate disc space until fusion occurs.

5. **Substantial equivalence claimed to predicate devices**
Daytona Anterior Cervical Cage is substantially equivalent to the predicate devices in terms of intended use, design, materials used, performance and function.

6. **Intended Use:**
The Daytona Anterior Cervical Cage system is indicated for use in skeletally mature patients with degenerative disc disease (DDD) of the cervical spine with accompanying radicular symptoms at one disc level. DDD is defined as discogenic pain with degeneration of the disc confirmed by patient history and radiographic studies. Daytona Anterior Cervical Cage implants are used to facilitate intervertebral body fusion in the cervical spine and are placed via an anterior approach at the C2 to T1 disc levels using autograft bone. Daytona Anterior Cervical Cage implants are to be used with supplemental fixation. Patients should have at least six (6) weeks of non-operative treatment prior to treatment with an intervertebral cage.

7. **Non-clinical Test Summary:**

   The following tests were conducted per ASTM F2077 and ASTM F2267:

   - Static and dynamic compression
   - Static and dynamic torsion
   - Subsidence
   - Expulsion

8. **Clinical Test Summary**

   No clinical studies were performed

9. **Conclusions Nonclinical and Clinical**

   The Daytona Anterior Cervical Cage is substantially equivalent to the predicate devices in terms of indications for use, design, material, performance and function.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

SpineNet, LLC
% The OrthoMedix Group. Inc.
Mr. J.D. Webb
1001 Oakwood Boulevard
Round Rock, Texas 78681

AUG 25 2011

Re: K110733
Trade/Device Name: Daytona Anterior Cervical Cage System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class: Class II
Product Code: ODP
Dated: July 19, 2011
Received: July 22, 2011

Dear Mr. Webb:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act

or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): _____

Device Name: Daytona Anterior Cervical Cage System

The Daytona Anterior Cervical Cage System is indicated for use in skeletally mature patients with degenerative disc disease (DDD) of the cervical spine with accompanying radicular symptoms at one disc level. DDD is defined as discogenic pain with degeneration of the disc confirmed by patient history and radiographic studies. These DDD patients may have up to Grade 1 spondylolisthesis or retrolisthesis at the involved level(s). The Daytona Anterior Cervical Cage System is used to facilitate intervertebral body fusion in the cervical spine and are placed via an anterior approach at the C2 to T1 disc levels using autograft bone. The Daytona Anterior Cervical Cage System is to be used with supplemental fixation. Patients should have at least six (6) weeks of non-operative treatment prior to treatment with an intervertebral cage.

Prescription Use X (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K110733